APPENDIX A. SEARCH STRATEGIES

DATABASE SEARCHED & TIME PERIOD COVERED:

PubMed – From 01/01/2010 to 03/18/2021

SEARCH STRATEGY: 879 results

(Total Quality Management[MESH] OR Quality Improvement[Mesh]) OR (CQI[Title/Abstract] OR "Continuous Quality Improvement"[Title/Abstract] OR "Quality Improvement" [Title/Abstract] OR "Lean Six Sigma"[Title/Abstract] OR "Clinical MicroSystems"[Title/Abstract] OR "Model for Improvement"[Title/Abstract] OR "lean management"[Title/Abstract] OR "lean thinking"[Title/Abstract] OR "lean healthcare"[Title/Abstract] OR "lean principles"[Title/Abstract] OR Toyota[Title/Abstract] OR IHI[Title/Abstract])

DATABASE SEARCHED & TIME PERIOD COVERED:

CINAHL – From 01/01/2010 to 03/30/2021

SEARCH STRATEGY: 1068 results

MH Quality Improvement OR TI (CQI OR "Continuous Quality Improvement" OR "Quality Improvement" OR "Lean Six Sigma" OR "Clinical MicroSystems" OR "Model for Improvement" OR "lean management" OR "lean thinking" OR "lean healthcare" OR "lean principles" OR Toyota OR IHI OR "system redesign" OR Total Quality Management”) OR AB (CQI OR "Continuous Quality Improvement" OR "Quality Improvement" OR "Lean Six Sigma" OR "Clinical MicroSystems" OR "Model for Improvement" OR "lean management" OR "lean thinking" OR "lean healthcare" OR "lean principles" OR Toyota OR IHI OR "system redesign" OR “Total Quality Management”)

DATABASE SEARCHED & TIME PERIOD COVERED:

DARE – From 01/01/2010 to 03/31/2015

SEARCH STRATEGY: 78 results

MeSH descriptor: [Quality Improvement]

OR

(CQI OR "Continuous Quality Improvement" OR "Quality Improvement" OR "Lean Six Sigma" OR "Clinical MicroSystems" OR "Model for Improvement" OR "lean management" OR "lean thinking" OR "lean healthcare" OR "lean principles" OR Toyota OR IHI OR "system redesign" OR “Total Quality Management”)

DATABASE SEARCHED & TIME PERIOD COVERED:

Cochrane – From 01/01/2010 to 03/30/2021

SEARCH STRATEGY: 54 results

MeSH descriptor: [Quality Improvement]

OR

(CQI OR "Continuous Quality Improvement" OR "Quality Improvement" OR "Lean Six Sigma" OR "Clinical MicroSystems" OR "Model for Improvement" OR "lean management" OR "lean thinking" OR "lean healthcare" OR "lean principles" OR Toyota OR IHI OR "system redesign" OR “Total Quality Management”)

APPENDIX B. FULL-TEXT SCREENING FORM

1. Is this an include? *Select all that apply.*

- ☐ a. Include: systematic review describes comparative effectiveness of CQI frameworks/methods
- ☐ b. Include: systematic review describes effectiveness of CQI framework(s)/method(s) SPECIFY HERE:
- ☐ c. Include: SR describes context/factors contributing to the success or failure of CQI framework(s)/method(s)
- ☐ d. Exclude (second tier): subset of included articles address key questions
- ☐ e. Exclude: this SR does not answer a KQ nor does it present data from included studies to address KQs STOP HERE
- ☐ f. Exclude: not a systematic review STOP HERE
- ☐ g. Unclear/to discuss STOP HERE
- ☐ h. DUPLICATE

2. Total number of studies included in the review

3. Number of included studies identified as CQI/QI in each study design category:

- ☐ Case study/case series with no formal analysis (fill in number)
- ☐ Pre/post (fill in number)
- ☐ Time series or concurrent comparator design (fill in number)
- ☐ RCT (fill in number)
- ☐ Qualitative analysis addressing KQ (fill in number)
- ☐ Other/not reported (fill in number)

IF YES TO 1A, 1B, 1C above, continue:

4. What were the **search dates** for this review (NR if not reported):

5. What **health conditions** were included:

- a. Specific population as inclusion/exclusion criteria for review:
- b. Varies/not reported/unclear

6. What **healthcare settings** were included:

- a. Specific setting as inclusion/exclusion criteria for review:
- b. Varies/not reported/unclear

7. What **regions/countries/geographical areas** were included:

- a. Specific areas/countries as inclusion/exclusion criteria for review:
- b. Varies/not reported/unclear

8. What **outcomes** were reported? *Select all that apply*

- a. Clinical/patient level
- b. Provider level (satisfaction, experience, etc)
- c. System/efficiency (e.g. wait times, length of stay, etc)
- d. Patient safety outcome (HAIs, harms, Costs)
- e. Various/other
- f. Not reported/unclear

9. Main findings (can copy/paste from abstract results/findings)

10. Did review have a definition or citation for CQI? *Select all that apply*

- a. Yes; a definition or citation for CQI was described as background/conceptual frame
- b. Yes, a definition or citation for CQI was used as inclusion/exclusion criteria
- c. No
- d. Unclear/to discuss

APPENDIX C. CRITERIA USED IN QUALITY ASSESSMENT

1A. Did the research questions and inclusion criteria for the review include the population/setting?

- Yes
- No
- To Discuss

1B. Did the research questions and inclusion criteria for the review include the intervention?

- Yes
- No
- To Discuss

1C. Did the research questions and inclusion criteria for the review include the comparator(s)?

- Yes
- No
- To Discuss

1D. Did the research questions and inclusion criteria for the review include the outcomes?

- Yes
- No
- To Discuss

2. Did the report of the review reference a protocol or PROSPERO registration?

- Yes
- No

3. Did the review authors explain their selection of other study designs (non-RCTs) for inclusion in the review?

- Yes, justification given
- No

4. Did the review authors use a comprehensive literature search strategy?

searched at least 2 databases (relevant to research question) provided key word and/or search strategy conducted search within 24 months of publication of the review

- Yes
- No

5. Did the review authors perform study selection in duplicate?
For yes, either ONE of the following:
at least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include
OR two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer

- Yes
- No

6. Did the review authors perform data extraction in duplicate?
For yes, either ONE of the following:
at least two reviewers achieved consensus on which data to extract from included studies
OR two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer

- Yes
- No

7. Did the review authors provide a list of excluded studies and/or justify the exclusions? (list of available excludes with reasons or flow with count of excludes by individual exclusion criteria categories for abstract and full-text excludes)

- Yes
- No

8A. Did the review authors describe the described populations/settings for individual included studies in adequate detail? (e.g. an evidence table)

- Yes
- No
- To Discuss

8B. Did the review authors describe the described interventions for individual included studies in adequate detail? (e.g. an evidence table) - *need components, not just brand name of intervention.*

- Yes
- No

- To Discuss

8C. Did the review authors describe the described comparators for individual included studies in adequate detail? (e.g. an evidence table)

- Yes
- No
- To Discuss

8D. Did the review authors describe the described outcomes for individual included studies in adequate detail? (e.g. an evidence table) - *not looking for numbers but need clarity (not "improve patient care", for example)*

- Yes
- No
- To Discuss

8E. Did the review authors describe the described research designs for individual included studies in adequate detail? (e.g. an evidence table)

- Yes
- No
- To Discuss

9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review? (because of topic/nature of interventions, criteria aren't relevant)

- Yes, do use and report tool used
- No

10. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?
For Yes:
included only low risk of bias RCTs
OR, if RCTs with moderate or high RoB, or NRSI were included the review provided a discussion of the likely impact of RoB on the results

- Yes
- No

11. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?
For Yes:
There was no significant heterogeneity in the results
OR if heterogeneity was present the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review (can be narratively discussed)

- Yes
- No

12. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?

For Yes:
performed graphical or statistical tests for publication bias or discussed the likelihood and magnitude of impact of publication bias

- Yes
- No
- N/A, not a quantitative synthesis

We have excluded question 12 from our AMSTAR table because all reviews were marked "N/A, not a quantitative synthesis".

13. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?

- Yes
- No

APPENDIX D. PEER REVIEW DISPOSITION

Reviewer	Reviewer Comments	Author Responses
Executive Summary		
2	page 7, lines 8-9, not sure how being the largest integrated system is an incentive in and of itself to improve quality/safety. Not getting what aspect here is the incentive.	Edited to read, '***As part of its mandate to optimize health outcomes for Veterans***, the Department of Veterans Affairs (VA) has an incentive to improve the quality and safety of health care'. This was also changed in the Introduction.
2	Lines 28-29, are both the Model for Change and Clinical Microsystems IHI's? Thought clinical microsystems were another approach or model, but not IHI's. Would be good to clarify. Actually, if both are IHI, no change would be needed.	Switched order of Model for Change and Clinical Microsystems to identify Model for Change as only IHI approach - '***Clinical Microsystems*** or the Institute for Healthcare Improvement (IHI)'s Model for Change'
2	page 8, why are DARE search dates truncated to 2015?	Bibliographic records published on DARE ceased at the end of March 2015. These databases can still be accessed but have not been and will not be updated.
2	page 9, line 5, should add "and" before the final condition	Added as suggested
2	Line 21-22, grammatical glitch, need to be either "had a modified AMSTAR2 rating" or "had modified AMSTAR2 ratings."	Removed as suggested
2	Line 34, should be "satisfaction was studied."	Replaced as suggested
2	page 10, line 19, need to decide on use of VA vs. VHA for consistency throughout (was VHA just a few lines above on line 11).	Changed to 'VA' throughout.
2	Lines 23-24, would move "not" before the "with one exception" for ease in interpretation (have not, with one exception,...).	Moved as suggested
7	Abbreviations Table: This review uses so many abbreviations – could you limit their use if word count is not an issue? Check the abbreviations table for "L = Lean" does not seem correct – pg. 4, line 58	Thank you for your comment. We have reduced the abbreviations throughout.
7	Could you explain an AMSTART2 rating of 2 (pg. 2, line 51) and the AMSTAR2 rating of 8 (pg. 3, line 23) (page 3, line 54) for I had to go looking for information in the text.	The following was added to the Executive Summary under Data Abstraction and Quality Assessment, ***'Each systematic review was assessed using a modified version of the Assessing the Methodological Quality of Systematic Reviews 2 (AMSTAR2) criteria [4]. This 16-item tool was designed to assess the***

		methodological quality of systematic reviews. As some AMSTAR2 items concern meta-analysis, we adapted the tool for this review, resulting in a 13-item tool. Assessment of studies using our modified tool was also completed in duplicate, with discrepancies resolved with group discussion. No study was excluded from analysis based on AMSTAR2 score; however, we chose a score of greater than or equal to 8 to represent higher quality systematic reviews. Studies based solely on qualitative analysis were not scored with the modified tool.'
7	Please spell out/explain OECD countries and why this was pertinent for the review (page 4, line 10)	Added the following, 'conducted in ***Organisation for Economic Co-operation and Development*** countries, ***which are a group of 38 countries with mature economies and, often, well-financed healthcare systems***,'
7	How many were performed with veteran populations (pg. 4, line 11)?	No SR was performed solely in veterans; however, individual studies often were performed in veteran populations. We did not track the full number of these included individual studies as part of this work. We did add 'some ***individual studies*** were performed with Veteran populations, which improves applicability to VA' earlier in the Discussion to clarify.
7	You don't abbreviate to CQI in first line of conclusion (pg. 4, line 23) or on lines 32, 35. I prefer it spelled out in the executive summary.	Removed CQI abbreviations from Executive Summary.
7	Could you explain the publication bias (e.g., only successful studies were ultimately published (pg. 4, line 27)?	Added '***as it is probable unsuccessful quality improvement work is less likely to receive publication'***.
7	Could you explain what a high AMSTAR 2 rating (e.g., 8 or higher) on pg. 4 line 38	Please see comment above.
Introduction		
2	Page 12, lines 12-14, not sure of intent or meaning of "particularly in settings with fewer currently trained personnel..." As opposed to what?	Modified to the following, 'particularly in settings ***such as individual clinics or units that may have*** fewer currently trained personnel to support project leadership and management'
7	Could you expand on why Lean was selected by the VA in 2019? Was this because it is the most popular, or for other reasons (pg. 6, lines 27-28). Would help the reader appreciate why this review was requested after the decision was made (versus before).	Unfortunately, we do not have any information about the history of why Lean was selected by the VA beyond what was shared with us in the topic nomination brief.
Methods		

2	Page 14 (of document, appears to be page 8 of report, so other page references above are of the document itself), "rejected ... publications that only reported components of QI without a full QI framework." Could the authors clarify the volume of publications that fell in this category and consider the implications of not having a "full QI framework"? This phrase leaves me wondering what was left out and how much I should be concerned about it.	Since the scope of the review was to discuss CQI frameworks/methods, any publications that only mentioned components of QI (such as checklists, or audit and feedback) would not address either of the key questions and therefore were excluded from our review. Out of 165 publications excluded at abstract phase, 34 publications were excluded for not discussing a CQI framework/method. Some of these focused on specific QI components without an overarching framework or strategy, while others focused on interventions that did not describe themselves as CQI or match the description of CQI described by Rubenstein and colleagues (e.g., in-hospital interventions to reduce diabetes readmissions).
2	Lines 27-28, grammatical glitch "were not get assessed..." (take out word "get"). There are just enough of these kind of glitches that I recommend a thorough re-read by the authors to ensure they address any I missed.	Deleted this specific example, as well as further editing on full document
7	Did you work with a librarian to validate the search method?	Yes, a librarian at the UCLA Library was one of our co-authors and team members. We added the following under the Search Strategy section, "***Our team, which included a medical librarian, developed and*** conducted broad systematic review searches using terms…"
7	What is the DARE database and why only searched until 2015?	Bibliographic records published on DARE ceased at the end of March 2015. These databases can still be accessed but have not been and will not be updated.
7	Pg. 11 – line 11: You don't abbreviate key questions – which is much better. Can you change the KQ in the figure 1 lit review to key questions and throughout the document?	We changed the abbreviations throughout.
Findings		
2	Literature flow, page 15, recommend past tense for "does not address key questions" etc. (line 11) since this section is otherwise in past tense. Same for line 13.	Changed as suggested
2	Figure 1 typo lines 10-12 "de-depulication" ?? (assume they mean de-duplication).	Changed as noted
2	What does RefMine mean?	RefMine stands for "reference mining." It involves using bibliographies of a source to find more related sources. We have added language in text to clarify the addition of articles by reference mining, or "RefMine".
2	Would be helpful if Figure 2 was self-documenting (e.g., what is SS only? line 12).	Edited figure to reflect this.

2	Page 19, line 50, typo "this has meant the even..." should be "that even". Time spent on this level of a read is going to exceed time available, so urge authors to do a very careful read-through to remedy these grammatical and typographical errors throughout.	Changed as noted
2	page 23, line 35, should be "reviewed implementation [in] emergency setting..."	Added as noted
2	Line 55 "general categories of care" an e.g., would be helpful.	Added the following, 'general categories of care, ***such as 'productivity' and 'clinical quality'*.**
2	page 25, lines 25-36 appears to be a single sentence and it is very hard to read through and stay on top of.	Regrettably, this may be a computer glitch. We apologize for the inconvenience!
3	I would include as an appendix a table of all of the included studies with their respective quality ratings, broken down by criterion in other words, "show us the math" when it comes to the calculation of the quality rating for each study. The benefit of this is that, if necessary, a can be used in follow on analyses to more granularly assess the effect of these interventions (for example, via network meta-analysis; see comment #4 below)). Along related lines, p. 11 lists in text how many reviews received a given AMSTAR2 rating. This information is better conveyed through a histogram.	We have added a table with AMSTAR2 ratings, as well as more discussion of the scores.
4	Minor issue on page 19: in the paragraph at the top of the page, a review is quoted as "having no more than 3.4 million defects per opportunity…" There is something wrong here, because it should be the other way around – not having more than 1 defect per 3.4 million opportunities	Thank you for noting this, as this was a direct quote from the referenced article. We have removed the quotations from this error and corrected the statement as follows, 'as having ***no more than one defect per 3.4 million opportunities '***may not be realistic or applicable to many QI issues faced by health care organizations'.
5	Page 10, Figure 1 - RefMine is included in the figure but it not referenced in the text. Please explain the addition of articles by RefMine in the literature flow.	We have added language in text to clarify the addition of articles by reference mining, or "RefMine".
7	Pg. 13, line 37: Can you explain reference mining and why this article was not captured using the review methods?	We have added language in text to clarify the addition of articles by reference mining, or "RefMine". The article in question was identified by reference mining and not our searches because it was published prior to the dates specified in our search. Given that our search did not identify any literature within the desired time frame addressing KQ1A, this publication merited inclusion despite its age.
7	Pg. 17, line 26 – which National Health Service? Same on Pg. 18., lines 34-45	The UK National Health Service; we have inserted this in the report.

7	Pg. 19, line 37 – double negative is hard to read	We have revised this sentence.
7	Pg. 20, line 27 – what is a QIC? At this point I'm so overwhelmed by the abbreviations…	QIC is Quality Improvement Collaborative. We have streamlined the number of abbreviations throughout for readability.
7	Pg 23, line 26: typo "review" not reviewed	Edited to read as follows, 'reviewed ***the*** included articles'
7	Pg 25, line 45 – typo – check font on multiple strategies	Regrettably, this may be a computer glitch. We apologize for the inconvenience!
7	Page 26, line 51 – mention why the five articles were not rated using the AMSTART2	We provided explanation in text.
7	Page 27, line 21-22. The sentence "no systematic reviews addressed Veterans" is confusing. I'm assuming you mean there was not a specific review that focused exclusively on Veterans or VHA, but there were a couple studies that were VA based included. Rewording would help comprehension.	Reworded to the following, 'No systematic reviews specifically addressed ***care of*** Veterans ***as a study objective nor*** were ***any*** conducted fully in VA ***settings***, although several ***individual*** articles within ***the included*** systematic reviews were based at VA
Discussion		
3	This may be an issue of systematic review writing style, but I could have done with a bit more discussion, reflection, interpretation, and recommendations for future directions. For example, one of the most important points I think that the authors make is the idea that there seems to be no one best way to conduct quality improvement in an organization. That is certainly consistent with current frameworks and implementation science, as well as general theries of organizational development and change. And this is a conclusion that really stands beyond the Powell et al. 2008 study; this conclusion is appropriately reached by the preponderance of evidence of a single studies of the studies that tested the effectiveness of single interventions as well.	We have expanded the following sections: Limitations, Study Quality, Applicability to VA, Research Gaps/Future Research, and Conclusions.
3	In another part of the conclusions the authors state: "Few systematic reviews included in this review of reviews had high ratings on a modified AMSTAR2 tool, leading us to conclude the overall quality of evidence related to these topics is low-to-moderate." Why is that? Why are so many QI studies of low to moderate quality? The cynic might answer, "because there was no IRB holding these QI teams to the rigorous standards of research." A more pragmatic answer, however, is likely that change is messy. In other words quality improvement must be tested in situ, not a laboratory,	We have renamed the 'Study Quality' section **'Quality of Included Reviews'** to clarify that we are not referring to quality of individual studies but rather, overall quality of systematic reviews. We have expanded this point, which now reads, ***'These low ratings on the AMSTAR2 tool leads us to conclude the overall certainty of evidence related to these reviews is low-to-moderate.'*** ***Reasons for the low AMSTAR2 scores of identified reviews may include underlying issues with study design and implementation in the primary QI literature, as well as with study reporting. Most QI initiatives are designed and implemented in pragmatic clinical***

	in order to fully understand its effectiveness in this setting question. Certainly the aforementioned suggestion to include the breakdown of quality ratings by criterion for each study (see comment #1, above) would be helpful in better understanding what is going on with respect to study quality.	***or operational settings, which may limit overall study quality for inclusion into a systematic review. Even when sufficient elements are included in QI projects, however, the elements may not be fully explained in subsequent manuscripts. These issues may then be compounded in performing and reporting systematic reviews.'*** We have also added a table re: AMSTAR2 information (Table 2).
3	Related to the study quality and future directions points, perhaps an appropriate future direction is to adopt a more meta-analytic approach to answering these evidence synthesis questions. In other words, (to be clear: not for the systematic review, but rather for the follow on study that should come next) the suggestion is to be analyze the included studies (and since this is a review of reviews, I would go so far as to say to use the original empirical studies included in the reviews examined) according to their individual study quality characteristics, and try to come up with some effect sizes with study quality accounted for. This approach is in many ways a analogous to the Hunter and Schmidt style of meta-analysis, which in psychological studies accounts for the reliability and validity of the criterion and predictor variables of each study as moderators and the overall meta-analysis, thereby yielding a more nuanced assessment of effect size.	This section has been expanded to now include, '***The most notable of these gaps is a lack of comparative studies analyzing multiple continuous quality improvement methodologies within healthcare settings. Although such comparative examples may be identifiable in other fields, such as manufacturing, the complexity of healthcare processes and the variability in local contexts for implementation of QI methodologies within healthcare warrants creation of such studies. As noted above, current VA efforts from resources such as the EBQI or LEAP programs may provide opportunities to promote such comparative investigations. An alternative approach would be to attempt meta-analysis of multiple continuous quality improvement methodologies with narrow questions in specific settings from the existing primary literature, such as waiting times in emergency departments. However, given the limitations of the systematic reviews in our review of reviews, such an initiative would likely require sharing and re-analysis of the primary data from the original studies.'***
4	On page 29, the section on "Research Gaps/Future Research" seems underdeveloped. It would be helpful to go on to provide detail about the "several gaps" noted in the one sentence in that section, which seems like it should be a topic sentence of a full paragraph.	Please see the above response.
7	Since the only paper describing comparative effectiveness was found using reference mining because it was a report and not indexed, you should address how this may have impacted your overall findings	This study was identified via reference mining as it was excluded from original searches given its age. We have added the following to highlight this, '***The single study explicitly discussing comparative effectiveness was identified via reference mining given its age. We chose to include this article, despite not making our publication date cut-off, as it was the only study we identified directly address the first Key Question.***'

7	Pg. 28, line 5-6: can you explain why OECD countries improves the applicability to VHA?	We have added the following, 'Organisation for Economic Co-operation and Development (OECD) countries, ***which generally have well-funded healthcare systems and*** improves applicability to VA'.
7	Research gaps/future research: Pg 29, lines 17-19 -This is where work from outside healthcare would be beneficial. Could you briefly look to see if other industries have compared CQI methods. If yes, which came out on top. If no, can you include possible reasons why this work is challenging and research methods that could address these questions.	This is an important note, although we feel work from outside healthcare is likely ungeneralizable into a healthcare context given the difference in contexts and outcomes and complexity of healthcare workflows. We did attempt to address this point as follows, '***The most notable of these gaps is a lack of comparative studies analyzing multiple continuous quality improvement methodologies within healthcare settings. Although such comparative examples may be identifiable in other fields, such as manufacturing, the complexity of healthcare processes and the variability in local contexts for implementation of QI methodologies within healthcare warrants creation of such studies.***
5	However, the conclusion is unsatisfying as it leaves the reader without a map for next steps. What are the next steps from here? What is a reader to do if one wants to determine the most effective improvement methodology? Consider adding to the discussion if there are comparative effectiveness studies of continuous quality improvement outside of healthcare. Can we learn something from another industry about reporting on CQI that we can apply in future effectiveness studies of CQI in healthcare?	Please see the amended section and comment above.
General/Misc.		
1	Are there any published or unpublished studies that we may have overlooked?: Yes - Work by Michael Parchman on Practice Facilitation REview QUERI Learning Hubs to determine if any of them also provide training in QI methodologies- notably LEAP, EBQI, Quality Scholars, Facilitation, LOCI, etc- see full list here: https://www.queri.research.va.gov/training_hubs/default.cfm Conceptual work by Friedman on the Learning Health System cycle	One article of Dr. Parchman's was included in a systematic review we included in this study (Hill, 2020). However, as he has not performed any systematic reviews, these other works would not have been eligible for inclusion in this project. Such issues with literature inclusion/scope are certainly limitations of the review of reviews approach, as we have emphasized in the Limitations as follows, ***'Similarly, one limitation of the review of reviews approach is an inability to closely align the inclusion criteria or scopes of the individual systematic reviews***'. We have added the following to the 'Applicability of Findings to the VA Population' section, '***Within VA, there are several ongoing initiatives that use continuous quality improvement methodologies or frameworks with continuous quality improvement elements, such as the Evidence-Based Quality Improvement (EBQI) Training Hub and The Learn. Engage. Act. Process. (LEAP) Program, in addition***

		to the focus on Lean in systems redesign. These current efforts may not be represented universally in the published literature, nor were any of these initiatives specifically identified in the systematic reviews that comprised this review of reviews, limiting our ability to discuss comparisons with other strategies. However, these initiatives may provide opportunities for comparative evaluations of continuous quality improvements methods.' We also added the following to the Conclusions, ***'Future work should emphasize comparative designs for continuous quality improvement methodologies. Available resources at VA may help facilitate such work in the future.***'
1	This is a very thorough review. The authors should also consider framing their findings within the context of current VHA initiatives around knowledge translation and HRO, which are part of the VHA Long-range goal of innovating as a learning and teaching organization. For example, it might be good to see which program offices (e.g., QUERI training programs, NCPS, NCOD, etc) are training others or using some of the 'necessary, but not sufficient' conditions for successful implementation of CQI: human resources, provider (MD) involvement), sustained managerial focus, etc. etc	Please see the latter half of the above comment.
2	Minor comment on TEP: Dr. Godwin is not just at Baylor -- she is a VA researcher as well, and leads the National VA Quality Scholars Coordinating Center. Unintentionally may misrepresent her as unattached to VA. May want to consider adding her VA title and adding academic titles to other TEP members as well. Small thing is that you refer to some folks as being from the VA Greater LA Healthcare System but describe the ESP as not. May want to consider adding GLA to the WLA reference.	We have edited this section to reflect the appropriate titles, thank you!
2	Minor comment on Peer Reviewers: When I have been a TEP member on this and other ESP reports, it is not uncommon for me to be asked to peer review the report as well. So when I see the section on peer reviewers, it makes me wonder if those are indeed the same as TEP or a mix of TEP and non-TEP. Might be useful to clarify.	Thank you for your comment. ***We have added, 'Technical Panel Experts are often asked to also serve as peer reviewers, but we also invite experts who have not been involved with the current project to serve as peer reviewers.'***

2	A brief summary of what the improvements would be might be helpful to make it easier for other professionals in this space to refer to when designing, conducting, and writing up their work -- actually, given that such guidelines exist, the authors may want to add a sentence about re-emphasizing their use in the field. The report would benefit from a very careful re-read by one of the authors for typos/grammatical glitches. I worked to include all I saw but may not have caught them all.	We have added the following to the Research Gaps / Future Research section, ***'The overall evidence base would be improved if future reported individual QI studies more closely adhered to SQUIRE 2.0 reporting standards. Similarly, future systematic reviews of these works would be stronger by considering the AMSTAR2 categories we found to be often lacking, such as specifying comparators as an inclusion criteria and sharing the results of comparators from individual trials, PROSPERO registration, and explicitly discussing risk of bias.'***
2	page 21, lines 46, reference to "trust pharmacies" and "trust systems" -- suspect these are from NHS type system but for a US readership, it would be helpful to add a definition or e.g., or something. Similarly, it would be helpful if the authors did a read-through/search to make sure that each abbreviation is spelled out on first use. There is inconsistency in how this is handled (e.g., ED vs. emergency department) -- many of these are not in the table of abbreviations, which is fine because you do not want readers to have to continue to go back to the table frequently. There are also variations in tense that warrant attention, e.g., page 22, line 7, two studies..."look at Lean strategies," while the next section is past tense "both review found..."	Your intuition was correct and we have added '***National Health Service'*** to clarify the language around trusts. Thank you for the other careful edits – we have clarified the abbreviations and abbreviations table and attempted to clear the remainder of the typos with this draft.
2	Ref #1 is incomplete. I did not go through the rest but omission on the 1st reference suggests all should be re-reviewed for completeness.	Thank you for your comment. We have reviewed all references.
3	I would also try to model the behavior the authors lamented being absent in some of the studies that they themselves review: put together an AMSTAR2 checklist and use it as a reporting standards checklist for this review of reviews (the same way one would include a PRISMA checklist for a meta-analysis	Thank you for your suggestion. We are unaware of the existence of such a tool for a review of reviews. We have included in our report the areas that may apply from the AMSTAR2 tool, such as registration of our protocol and duplicate data collection. However, as many aspects of AMSTAR2, such as the appropriateness of meta-analytic techniques and risk of bias for included primary studies, do not apply to a review of reviews, we have created a list.
3	If resources and the structure of the reporting mechanism allow, it might be nice to create a more interactive version of this Appendix E table by which users could sort and filter that could be made available in addition.	Thank you for your comment. While a very interesting idea, we are unable to add interactive features to the reports at this time.
4	When I first read Key Questions 1A and 1B, I was unclear on how they differed (and may still be a bit unclear now). It	This is correct. We attempted to clarify under Topic Development, as follows, ***'To be eligible for Key Question 1A, a systematic review***

	seems like Key Question 1B still involved looking for indirect comparisons of effectiveness (at least, conclusions by authors of the studied systematic reviews regarding differential evidence of effectiveness between Lean and Six Sigma). For example, on page 15 (part of question 1B), it is noted that "None of the 11 reviews that included more than one CQI strategy reached a strong conclusion that any strategy was superior to any other(s)." If I understand Key Question 1A correctly, eligible reviews had to have to actually have comparative effectiveness as their stated focus? If the authors could do more to clarify the criteria for deciding how a study became eligible for Key Question 1A as opposed to being in Key Question 1B, that would be helpful.	***had to explicitly focus on comparative effectiveness of multiple continuous quality improvement methodologies as a stated aim. If a review commented on multiple methodologies but did not seek to compare the effectiveness of the strategies within its methods, it was included in Key Question 1B.***'
4	Given how frequently Lean and Six Sigma are discussed in the report, it would be helpful to provide a brief description of what constitutes a Lean approach or a Six Sigma approach. The directive to use Lean makes it important to define (in general terms) what constitutes a Lean approach, and since Six Sigma is one of the most popular alternatives to Lean, a brief definition of Six Sigma would be helpful as well.	We did not explicitly define each method for our search strategy, as we allowed each systematic review to categorize the included individual studies as the authors had chosen originally. This is now emphasized in the Study Selection section, ***'Specific definitions for each strategy were not included in our search strategy; rather, we allowed each systematic review to apply its own definitions to the included studies.***'
7	Pg 7, lines 56-59: A table listing the CQI strategies with a brief definition of each approach would enhance the readers understanding of each method. Appendix B does not include this information.	Please see above comment and response. We did not define strategies for this review of reviews and individual studies had considerable variability in their own definitions/discussion of strategies.
7	The big question is if any work has been done outside healthcare? The review was comprehensive but inconclusive. Is there knowledge from other fields that could inform healthcare? If yes, it should be briefly included in the review. If no, perhaps address why there is not work comparing CQI methods? Omitted evidence • Work outside of healthcare • Non-indexed program reports	Please see our earlier comment about work outside healthcare having poor generalizability to the healthcare context. We have expanded comments about other VA work that may help to answer these questions in the future, in addition to the expanded Research Gaps previously mentioned.

APPENDIX E. EVIDENCE TABLE

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
Aij, 2017[8]	**Search end date:** 2016 **Number of included studies:** 32 **Quality score:** 2	**Intervention:** Lean **Setting**: Not reported **Condition:** Not reported **Geographical region:** Not reported	This work contributes to the development of a new framework for describing leadership attributes within lean management of health care. Originality/value – The summary of attributes can provide a model for health care leaders to apply lean in their organizations.
Amaratunga, 2016[9]	**Search end date:** June 9, 2015 **Number of included studies:** 23 **Quality score:** 8	**Intervention:** Lean, Six Sigma, Lean/Six Sigma **Setting**: Radiology **Condition:** Not reported **Geographical region:** Varies across included studies	Of the 278 articles returned, 23 studies were suitable for inclusion. Of these, 10 assessed Six Sigma, 7 assessed Lean, and 6 assessed Lean Six Sigma. The diverse range of measured outcomes can be organized into 7 common aims: cost savings, reducing appointment wait time, reducing in-department wait time, increasing patient volume, reducing cycle time, reducing defects, and increasing staff and patient safety and satisfaction. All of the included studies demonstrated improvements across a variety of outcomes. However, there were high rates of systematic bias and imprecision as per the Grading of Recommendations Assessment, Development and Evaluation guidelines.
Andersen, 2014[42]	**Search end date:** 2012 **Number of included studies:** 18 **Quality score:** N/A	**Intervention:** Lean **Setting**: Not reported **Condition:** Not reported **Geographical region:** Varies across included studies	We provide a framework emphasising context by relating facilitators to domains and dimensions of capability. 23 factors enabling a successful lean intervention in hospitals were identified in the systematic review, where management and a supportive culture, training, accurate data, physicians and team involvement were most frequent.
Antony, 2018[40]	**Search end date:** 2016 **Number of included studies:** 68 **Quality score:** N/A	**Intervention:** Six Sigma **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	The findings of the systematic review reveal a growing interest in research on Six Sigma adoption in healthcare. The findings indicate that Six Sigma applications in healthcare have been focused on the entire hospital with no real focus on a particular department or function. The key findings on benefits, success factors, challenges and common tools of Six Sigma from the existing literature are also presented in the paper.
Bucci, 2016[10]	**Search end date:** NR **Number of included studies:** 9 **Quality score:** 5	**Intervention:** Lean **Setting**: Emergency department **Condition:** Not reported **Geographical region:**	Nine before-and-after studies met these eligibility criteria. Management of patient flow was the main intervention. Almost all studies showed EDs performance improvement: increased patient volume, decreased length of stay and number of patients left without

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
		Varies across included studies	being seen, reduced costs, and increased patient satisfaction. Only 1 case reported worse results after Lean intervention implementation.
Côté, 2020[11]	**Search end date:** 2018 **Number of included studies:** 35 **Quality score:** 9	**Intervention:** Clinical Microsystems **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Varies across included studies	The impact of the project was most often measured using a single metric (59.1%) that was operational (*eg*, waiting time). Although most Lean project publications reported the use of tools to "break down the problem" (84.4%, Step 2) and "see countermeasures through" (70.0%, Step 6), fewer than half described using tools associated with each of the other steps. Projects completed an average of 2.77 steps and none of the projects completed all steps. Although some may perceive low adherence to the tenets of Lean as a deficiency, it may be that Lean approaches are evolving to better meet the needs of healthcare.
Crema, 2017[36]	**Search end date:** March 2014 **Number of included studies:** 16 **Quality score:** N/A	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Varies across included studies	Sixteen articles were included in the analysis. Links between the identified LHM [Lean Healthcare Management] purposes of adoption and CW objectives were discovered: through process understanding, optimization, evaluation and control, LHM contributes to the reduction of overuses in healthcare, but also to the delivery of a more effective and evidence-based care (EBC). Moreover, it provides an objective approach useful for choosing the most cost-effective solution among different alternatives.
D'Andreamatteo, 2015[39]	**Search end date:** September 2013 **Number of included studies:** 243 **Quality score:** N/A	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	243 articles were selected for analysis. Lean is best understood as a means to increase productivity. Hospital is the more explored setting, with emergency and surgery as the pioneer departments. The USA appears to be the leading country for number of applications. The theoretical works have been focused mainly on barriers, challenges, and success factors. Sustainability, framework for measurement and critical appraisal remain underestimated themes. Evaluations of "system wide approach" are still low in number.
Dellifraine, 2010[12]	**Search end date:** June 2009 **Number of included studies:** 34 **Quality score:** 5	**Intervention:** Lean, Six Sigma, and Lean/Six Sigma **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Not reported	The authors identified 177 articles on SS/L published in the last 10 years. However, only 34 of them reported any outcomes of the SS/L projects studied, and less than one-third of these articles included statistical analyses to test for significant changes in outcomes.
DelliFraine, 2013[13]	**Search end date:** May 2012	**Intervention:** Six Sigma **Setting**: Varies across	The authors identified 310 articles on SS published in the last 15 years. However, only 55 were empirical peer-reviewed articles, 16 of

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
	Number of included studies: 55 **Quality score:** 5	included studies **Condition:** Varies across included studies **Geographical region:** Not reported	which reported the correct use of SS. Only 7 of these articles included statistical analyses to test for significant changes in quality of care, and only 16 calculated defects per million opportunities or sigma level. This review demonstrates that there are significant gaps in the Six Sigma health care quality improvement literature and very weak evidence that Six Sigma is being used correctly to improve health care quality.
Dzidowska, 2020[14]	**Search end date:** September 2018 **Number of included studies:** 56 **Quality score:** 9	**Intervention:** CQI method **Setting**: Primary care **Condition:** Alcohol misuse **Geographical region:** Varies across included studies	Fifty-six papers representing 45 projects were included. Of these, 24 papers were randomized controlled trials, 12 controlled studies and 20 before/after and other designs. Most reported on strategies for improving implementation of screening and brief intervention. Only 6 addressed relapse prevention pharmacotherapies. Only 5 reported on patient outcomes and none showed significant improvement. The 3 essential CQI method elements were clearly identifiable in 12 reports. More studies with 3 essential CQI method elements had implementation and follow-up durations above the median; utilised multifaceted designs; targeted both practice and health system levels; improved screening and brief intervention than studies without the CQI method elements.
Glasgow, 2010[15]	**Search end date:** July 15, 2010 **Number of included studies:** 37 **Quality score:** 5	**Intervention:** Lean, Six Sigma, Lean Sigma **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Not reported	Database searches identified 539 potential articles. After review of titles, abstracts, and full text, 47 articles met inclusion criteria: 10 articles summarized multiple projects, 12 reported Lean projects, 20 reported Six Sigma projects, and 5 reported Lean Sigma projects. Generally, the studies provided limited data, with only 15 articles providing any sort of follow-up data; of the 15, only 3 report a follow-up period greater than 2 years.
Hill, 2020[16]	**Search end date:** February 23, 2019 **Number of included studies:** 28 **Quality score:** 11	**Intervention:** Continuous quality improvement vs non-continuous quality improvement **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	Twenty-eight RCTs assessed the effectiveness of different approaches to continuous quality improvement with a non-continuous quality improvement comparator in various settings, with interventions differing in terms of the approaches used, their duration, meetings held, people involved, and training provided. All RCTs were considered at risk of bias, undermining their results. Findings suggested that the benefits of continuous quality improvement compared to a comparator on clinical process, patient, and other outcomes were limited, with less than half of RCTs showing any effect. Where benefits were evident, it was usually on clinical process measures, with the model used (*ie*, Plan-Do-Study-Act, Model of

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
			Improvement), the meeting type (*ie*, involving leaders discussing implementation) and their frequency (*ie*, weekly) having an effect. None considered socio-economic health inequalities.
Hulscher, 2013[17]	**Search end date:** Week 2 of June 2009 **Number of included studies:** 23 **Quality score:** 6	**Intervention:** Quality Improvement Collaboratives **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Not reported	Of 1367 abstracts identified, 23 papers (reporting on 26 collaboratives) provided information on potential determinants and their relationship with effectiveness. We categorised potential determinants of success using the definition for collaboratives as a template. Numerous potential determinants were tested, but only a few related to empirical effectiveness.Some aspects of teamwork and participation in specific collaborative activities enhanced short-term success. If teams remained intact and continued to gather data, chances of long-term success were higher. There is no empirical evidence of positive effects of leadership support, time, and resources.
Isfahani, 2019[18]	**Search end date:** 2016 **Number of included studies:** 26 **Quality score:** 4	**Intervention:** Lean **Setting**: Emergency department **Condition:** Varies across included studies **Geographical region:** Varies across included studies	According to the studies, responsibility of organization's senior management and his/her supports; increasing the knowledge of the characteristics and dimension of lean among the providers of health service; and decreasing the resistance and consulting with external counselors can have great effect on the success of lean management
Leggat, 2015[19]	**Search end date:** April 2013 **Number of included studies:** 41 **Quality score:** 3	**Intervention:** process redesign methodologies **Setting**: Hospital **Condition:** Not reported **Geographical region:** Varies across included studies	Success factors for the changes included mechanisms to facilitate participation throughout the process, clearly documented protocols and expectations for the health professionals which were supported by education, mechanisms to audit and provide feedback on behaviours and performance, as well as being able to hold the participating health professionals accountable. The success of process redesign methodologies is found to be highly dependent on these performance-based human resource management (HRM) practices.
Maijala, 2018[37]	**Search end date:** February 2016 **Number of included studies:** 12 **Quality score:** N/A	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:**	Considering the results using the windshield concept emphasizes the philosophy, principles, and tools of Lean thinking. Lean leadership and management factors in health care were mainly conceptualized as skills and capabilities such as problem solving, making changes occur, empowering, communicating, coaching, supporting, facilitating, being democratic, organizational learning, and organizational

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
		Varies across included studies	success, all of which represented middle-stage or advanced managerial skills and capabilities.
Magalhães, 2016[20]	**Search end date:** March 2015 **Number of included studies:** 47 **Quality score:** 3	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	This study enabled us to show that Lean thinking in health is a management model that improves the structure, process and outcome, from the care and management actions. The principles of Lean thinking are widespread in various contexts of health, such as emergency, oncology, pharmacy, intensive care unit, radiology, orthopedics, mental health clinics, and cardiology services. The main impacts from the application of this thinking in health are increasing productivity and team efficiency; reduction in waiting time for patient care; standardization of care process, reducing costs, improved teamwork, reduction in the patient's hospital length; increasing the quality of service provided; increased patient satisfaction; increasing patient safety and health professionals; and employee satisfaction.
Mason, 2015[21]	**Search end date:** January 1, 2014 **Number of included studies:** 23 **Quality score:** 7	**Intervention:** Lean, Six Sigma, Lean/Six Sigma **Setting**: Surgical inpatients, ORs, or outpatient surgery clinics **Condition:** Surgical patients **Geographical region:** Varies across included studies	Of the 124 studies returned, 23 were suitable for inclusion, with 11 assessing Lean, 6 Six Sigma, and 6 Lean Six Sigma. The broad range of outcomes can be collated into 6 common aims: to optimise outpatient efficiency, to improve operating theatre efficiency, to decrease operative complications, to reduce ward-based harms, to reduce mortality, and to limit unnecessary cost and length of stay. The majority of studies (88%) demonstrate improvement; however, high levels of systematic bias and imprecision were evident.
Mazzocato, 2010[38]	**Search end date:** February 2008 **Number of included studies:** 33 **Quality score:** N/A	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Not reported	The authors reviewed 33 articles and found a wide range of lean applications. The articles describe initial implementation stages and emphasise technical aspects. All articles report positive results. The authors found common contextual aspects which interact with different components of the lean interventions and trigger 4 different change mechanisms: understand processes to generate shared understanding; organise and design for effectiveness and efficiency; improve error detection to increase awareness and process reliability; and collaborate to systematically solve problems to enhance continual improvement.
Moraros, 2015[22]	**Search end date:** NR **Number of included studies:** 22	**Intervention:** Lean **Setting**: Varies across included studies	Our electronic search identified 22 articles that passed methodological quality review. Among the accepted studies, 4 were exclusively concerned with health outcomes, 3 included both health

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
	Quality score: 5	**Condition:** Varies across included studies **Geographical region:** Varies across included studies	and process outcomes, and 15 included process outcomes. Our study found that Lean interventions have: (i) no statistically significant association with patient satisfaction and health outcomes; (ii) a negative association with financial costs and worker satisfaction, and (iii) potential, yet inconsistent, benefits on process outcomes like patient flow and safety.
Nadeem, 2013[23]	**Search end date:** April 2012 **Number of included studies:** 24 **Quality score:** 6	**Intervention:** Quality Improvement Collaboratives **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Varies across included studies	We found 14 crosscutting components as common ingredients in health care QI collaboratives (*eg*, in-person learning sessions, phone meetings, data reporting, leadership involvement, and training in QI methods). The collaboratives reported included, on average, 6-7 of these components. The most common were in-person learning sessions, plan-do-study-act (PDSA) cycles, multidisciplinary QI teams, and data collection for QI. The outcomes data from these studies indicate the greatest impact of QI collaboratives at the provider level; patient-level findings were less robust.
Nicolay, 2012[24]	**Search end date:** November 24, 2010 **Number of included studies:** 34 **Quality score:** 10	**Intervention:** Lean, Lean Six Sigma, Six Sigma, Total Quality Management, CQI method, Statistical Process Control or Statistical Quality Control, PDSA/PDCA **Setting**: Surgical settings **Condition:** Not reported **Geographical region:** Varies across included studies	Some 34 of 1595 articles identified met the inclusion criteria after consensus from 2 independent investigators. Nine studies described continuous quality improvement (CQI method), 5 Six Sigma, 5 total quality management (TQM), 5 plan-do-study-act (PDSA) or plan-do-check-act (PDCA) cycles, 5 statistical process control (SPC) or statistical quality control (SQC), 4 Lean, and 1 Lean Six Sigma; 20 of the studies were undertaken in the USA. The most common aims were to reduce complications or improve outcomes (11), to reduce infection (7), and to reduce theatre delay (7). There was 1 randomized controlled trial.
Niñerola, 2019[41]	**Search end date:** 2017 **Number of included studies:** 196 **Quality score:** N/A	**Intervention:** Six Sigma **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Not reported	(1) Six Sigma publications in healthcare sector have been carried out mostly in the USA, (2) multiple specialities and services have used this tool; among them, we can emphasize the operating room and radiology service, (3) the case study has been the most used methodology and, (4) the objectives are focused mainly on achieving reductions of time, costs and errors, for the improvement of the quality and the satisfaction of the patients.
Nunes, 2016[25]	**Search end date:** October 13, 2014 **Number of included studies:** 76	**Intervention:** CQI method **Setting**: Nephrology **Condition:** Kidney disease **Geographical region:**	We initially identified 468 publications; 40 were excluded as duplicates or not available/not in English. An additional 352 did not meet criteria for full review due to: 1. Not meeting criteria for inclusion = 196 (*eg*, reviews, news articles, editorials) 2. Not nephrology-

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
	Quality score: 5	Varies across included studies	specific = 153, 3. Only available as abstracts = 3. Of 76 publications meeting criteria for full review, the majority [45 (61%)] focused on ESRD care. 74% explicitly stated use of specific continuous quality improvement tools in their methods. The highest number of publications in a given year occurred in 2011 with 12 (16%) articles. 89% of studies were found in biomedical and allied health journals and most studies were performed in North America (52%). Only 1 was randomized and controlled although not blinded.
Powell, 2008[1]	**Search end date:** NR **Number of included studies:** 59 **Quality score:** 2	**Intervention:** TQM/continuous quality improvement, IHI/PDSA, Lean, SS **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	The 5 models are described and evaluated separately in order to bring out some important conceptual differences between them. In practice, however, distinctions between the models are not always clear-cut: there are many areas of overlap, with many of the approaches employing very similar tools and techniques. In implementation, health care organisations have tended to apply a combination of tools and approaches in a piecemeal and eclectic way. What the models do have in common is that they all require the same broad set of 'necessary, but not sufficient' conditions for successful implementation. These conditions emerge strongly from the studies reviewed in this report as well as from the broader literature on health service change. They include: the active engagement of health professionals, especially doctors; the active participation of middle and senior managers, and the support of board members; the use of multifaceted interventions and sustained action at different levels of the health care system; the alignment of quality improvement activities with the strategic goals of the organisation; and the embedding of quality improvement as an integral part of the everyday work of all staff (rather than as the responsibility of a separate directorate or team). Effective quality improvement work – whatever the model that structures this work – also needs to be supported by robust IT providing timely local data, and requires significant investment in staff training and development.
Schouten, 2008[26]	**Search end date:** June 2006 **Number of included studies:** 9 **Quality score:** 10	**Intervention:** Quality Improvement Collaboratives **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Not reported	Of 1104 articles identified, 72 were included in the study. Twelve reports representing 9 studies (including 2 randomised controlled trials) used a controlled design to measure the effects of the quality improvement collaborative intervention on care processes or outcomes of care. Systematic review of these 9 studies showed moderate positive results. Seven studies (including 1 randomised controlled trial) reported an effect on some of the selected outcome

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
			measures. Two studies (including 1 randomised controlled trial) did not show any significant effect.
Talib, 2011[27]	**Search end date:** 2009 **Number of included studies:** 15 **Quality score:** 2	**Intervention:** Total Quality Management (TQM) **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Varies across included studies	Eight supporting TQM practices, such as top-management commitment, teamwork and participation, process management, customer focus and satisfaction, resource management, organization behavior and culture, continuous improvement, and training and education were identified as best practices for TQM implementation in any health care setting.
Tlapa, 2020[29]	**Search end date:** December 2018 **Number of included studies:** 40 **Quality score:** 8	**Intervention:** Lean, Lean Six Sigma **Setting**: Ambulatory & ED settings **Condition:** Not reported **Geographical region:** Varies across included studies	According to our findings, LH [lean healthcare] helped to reduce waiting time and LOS in ambulatory care, mainly owing to its focus on identifying and minimizing non-value added (NVA) activities. Nevertheless, evidence of the impact of LH on patient/ staff satisfaction and the translation of the obtained benefits into savings is scarce among studies.
Trakulsunti, 2018[30]	**Search end date:** December 2016 **Number of included studies:** 24 **Quality score:** 5	**Intervention:** Lean, Six Sigma, Lean Six Sigma **Setting**: Hospital **Condition:** Medication errors **Geographical region:** Varies across included studies	A total of 24 studies were identified from the search meeting the criteria for the systematic literature review. Increased interest in the application of process excellence methodologies such as Lean, Six Sigma, and Lean Six Sigma to reduce medication errors, especially from the developed countries, was found. Several themes have emerged in this paper including: tools and techniques of Lean and Six Sigma in the context of medication errors, Lean and Six Sigma methodology, types of medication errors, Lean Six Sigma project selection, benefits, challenges, and success factors. The study is expected to benefit health care practitioners in implementing the Lean Six Sigma methodology to reduce medication errors.
Tricco, 2012[31]	**Search end date:** July 2010 **Number of included studies:** 142 **Quality score:** 9	**Intervention:** Compares CQI method to other methods **Setting**: Varies across included studies **Condition:** Diabetes **Geographical region:**	We reviewed 48 cluster randomised controlled trials, including 2538 clusters and 84 865 patients, and 94 patient randomised controlled trials, including 38 664 patients. In random effects meta-analysis, the QI strategies reduced HbA1c by a mean difference of 0·37% (95% CI 0·28–0·45; 120 trials), LDL cholesterol by 0·10 mmol/L (0·05–0.14; 47 trials), systolic blood pressure by 3·13 mm Hg (2·19–4·06, 65 trials), and diastolic blood pressure by 1·55 mm Hg (0·95–2·15, 61 trials) versus usual care. We noted larger effects when baseline

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
		Varies across included studies	concentrations were greater than 8·0% for HbA1c, 2·59 mmol/L for LDL cholesterol, and 80 mm Hg for diastolic and 140 mm Hg for systolic blood pressure. The effectiveness of QI strategies varied depending on baseline HbA1c control. QI strategies increased the likelihood that patients received aspirin (11 trials; relative risk [RR] 1·33, 95% CI 1·21–1·45), antihypertensive drugs (10 trials; RR 1·17, 1·01–1·37), and screening for retinopathy (23 trials; RR 1·22, 1·13–1·32), renal function (14 trials; RR 128, 1·13–1·44), and foot abnormalities (22 trials; RR 1·27, 1·16–1·39). However, statin use (10 trials; RR 1·12, 0·99–1·28), hypertension control (18 trials; RR 1·01, 0·96–1·07), and smoking cessation (13 trials; RR 1·13, 0·99–1·29) were not significantly increased.
Wackerbarth, 2021[32]	**Search end date:** NR **Number of included studies:** 295 **Quality score:** 4	**Intervention:** Lean **Setting**: Varies across included studies **Condition:** Not reported **Geographical region:** Not reported	The most frequent type of publication reported empirical research (48.6%) and most of these (80.3%) shared the results of the Lean projects. Of the 237 publications reporting Lean projects, more than half (71.3%) used an experimental, one-site, pre/postdesign. The impact of the project was most often measured using a single metric (59.1%) that was operational (*eg*, waiting time). Although most Lean project publications reported the use of tools to "break down the problem" (84.4%, Step 2) and "see countermeasures through" (70.0%, Step 6), fewer than half described using tools associated with each of the other steps. Projects completed an average of 2.77 steps and none of the projects completed all steps. Although some may perceive low adherence to the tenets of Lean as a deficiency, it may be that Lean approaches are evolving to better meet the needs of healthcare.
Woodnutt, 2018[33]	**Search end date:** NR **Number of included studies:** 12 **Quality score:** 4	**Intervention:** Lean **Setting**: Hospital **Condition:** Varies across included studies **Geographical region:** England	Lean has ostensible value but it is difficult to draw a conclusion on efficacy or sustainability. Higher-quality scientific research into Lean and the effect of staffing cultures on initiatives are needed to ascertain the extent that Lean can affect health care quality and subsequently be sustained.
Zamboni, 2020[34]	**Search end date:** June 2018 **Number of included studies:** 32 **Quality score:** 7	**Intervention:** Quality Improvement Collaboratives **Setting**: Varies across included studies **Condition:** Varies across included studies	We screened 962 abstracts of which 88 met the inclusion criteria, and we retained 32 for analysis. Adequacy and appropriateness of external support, functionality of quality improvement teams, leadership characteristics and alignment with national systems and priorities may influence outcomes of quality improvement collaboratives, but the strength and quality of the evidence is weak.

Author, year	Description of systematic review	Description of intervention*	Findings relevant to continuous quality improvement
		Geographical region: Varies across included studies	Participation in quality improvement collaborative activities may improve health professionals' knowledge, problem-solving skills and attitude; teamwork; shared leadership and habits for improvement. Interaction across quality improvement teams may generate normative pressure and opportunities for capacity building and peer recognition.
Zepeda-Lugo, 2020[35]	**Search end date:** 2019 **Number of included studies:** 39 **Quality score:** 9	**Intervention:** Lean, Lean Six Sigma **Setting**: Varies across included studies **Condition:** Varies across included studies **Geographical region:** Varies across included studies	Our findings show that by focusing on reducing non-value-added activities, LH contributed to improving patient flow and efficiency within inpatient care.

*Only the study by Hill et al sufficiently described comparators to receive credit in our modified AMSTAR review.

APPENDIX F. CITATIONS FOR EXCLUDED PUBLICATIONS

Does Not Discuss Key Questions, n=69

1. Agarwal, A., et al., Hospital-based quality improvement interventions for patients with heart failure: a systematic review. Heart (British Cardiac Society), 2019. 105(6): p. 431-438.
2. Alagoz, E., et al., The use of external change agents to promote quality improvement and organizational change in healthcare organizations: a systematic review. BMC health services research, 2018. 18(1): p. 42.
3. Antierens, A., et al., How much of Toyota's philosophy is embedded in health care at the organisational level? A review. Journal of Nursing Management (John Wiley & Sons, Inc.), 2018. 26(4): p. 348-357.
4. Atassi, K., Strategies to increase colorectal cancer screening. Nurse Practitioner, 2012. 37(7): p. 21-26.
5. Bahiru, E., et al., Hospital-Based Quality Improvement Interventions for Patients With Acute Coronary Syndrome: A Systematic Review. Circulation. Cardiovascular quality and outcomes, 2019. 12(9): p. e005513.
6. Bakker, F.C., S.H.M. Robben, and M.G.M. Olde Rikkert, Effects of hospital-wide interventions to improve care for frail older inpatients: a systematic review. BMJ quality & safety, 2011. 20(8): p. 680-691.
7. Bastemeijer, C.M., et al., Patient experiences: a systematic review of quality improvement interventions in a hospital setting. Patient related outcome measures, 2019. 10: p. 157-169.
8. Bergerum, C., et al., How might patient involvement in healthcare quality improvement efforts work—A realist literature review. Health Expectations, 2019. 22(5): p. 952-964.
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